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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,645	WELCH ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-19,23 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2, 3, 6, 23, and 28* is/are allowed.

6)☒ Claim(s) *1,7-19 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/03/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed April 24, 2006 in response to the Office Action of January 11, 2006 is acknowledged and entered. Claim 28 has been added, claims 4, 5, 21, 22, and 24 have been canceled, and claims 1-3, 6-19, 23, 25-28 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Group Art Unit 1648.

Claim Objections

The objection of claims 1, 21, 22 and 24 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim **is withdrawn** in view of Applicants cancellation of claims 21, 22, and 24.

Claim Rejections - 35 USC § 112

The rejection of claims 1-19, 23, 25-27 under 35 U.S.C. 112, first paragraph, for failing to reasonably provide enablement for the use of any depth filter under any condition to remove prion protein from a sample source, **is withdrawn** in view of Applicants' amendment to the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 7-19, and 25-27 under 35 U.S.C. 103(a) as being unpatentable over Nebe (WO 96/05846, IDS Paper No. 1), Omar et al. (U.S. Pat. No. 5,696,236, IDS Paper No. 1) and Savage et al. (EP 0 798 003 A2, IDS Paper No. 1) **is maintained** for reasons of record.

Applicants' arguments have been fully considered but fail to persuade. Applicant has amended claims 1, 17, 18 and 26 to include the transitional phrase "consisting essentially of " and "consists essentially of ".

The MPEP provides the following guidelines for treating transient claim language.

> MPEP 2100The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas *Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963*); Water Technologies Corp. vs. Calco*, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). **For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."** See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as

> constituting a material change in the basic and novel characteristics of the invention."). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of **"consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.** *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

In this instance Applicants' amendment to the claims does not alter the prior rejection because the transitional phrase "consists essentially of" is interpreted as "comprising". The amendment of claims to recite the transitional phrase "consisting essentially of " and "consists essentially of " does not overcome the instant rejection because the step of "passing a protein-contaning solution through a filter" does not distinguish the claimed invention over the prior art. Applicant did not indicate in the specification or the claims how the steps "consisting essentially of passing a protein-contaning solution through a filter" materially change the characteristics of Applicant's invention. Therefore, the rejection is maintained.

Nebe (WO 96/05846, IDS Paper No. 1) teaches the removal of prion form solution utilizing a series of membrane or ultramembrane filters. The method teaches using a prefilter of nylon gauze and nylon membrane filers ranging in size from 2.0 microns to 0.2 microns (see page 10). The filters can be arranged in a series. The reference indicated that prion particles can be removed from the liquid and as an additional benefit at the same time other infectious martial can be removed such as bacteria, viruses and endotoxins (page 6). The reference also teaches

that the prefilter alone removed half of the infectious agent (see page 13), indicating that the prion agent has a high binding affinity for the prefilter material. The reference also teaches that after the first ultra filtration alone the reduction in the prion protein was by a factor of $10^{4.67}$. The reference teaches that through the use a ultrafiltraion the prion titer can be reduced even further, the process can be set up as series of filtration steps with each step further removing more of the infections prion.

Omar et al. teaches separating virus from protein solution using an absorbent (binder) that is diatomaceous earth, perlite or kieselguhr (see claims). The method purifies a human blood plasma solution for the purpose of producing safe blood products (column 1, lines 10-30).

Savage et al. teach a method of removal of viruses from an aqueous liquid containing proteins, the method comprises the steps of passing the liquid though a depth filter formed of matrix comprising porous elements having a size 0.25 –2.0 microns.

It would have been obvious to one of ordinary skill in the art to utilize a depth filter, which are ordinarily used in the art as a prefilter for ultramembrane filtration (Savage et al. page 2, lines 47-48). The removal of prion particles from a liquid can be achieved based on the teaching of Nebe which indicated that half of the infectious prion was removed using the nylon premembrane filter (depth filter) indicating that the prion has a high nonspecific affinity for the prefiltration media. The claims as written are not limited to the use of only one type of filter. The method steps "comprise" the use of a depth filter, which is known in the art to be a prefilter, the claims can include other filtration steps to achieve the purpose of removing the prion protein from the sample. The transitional term "comprising," which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional,

unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004).

The claims are rejected as being obvious over the cited references.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 8, 9, 14, 16, 17, 18, 26 and 27 under 35 U.S.C. 102(b) as being anticipated by Nebe (WO 96/05846, IDS Paper No. 1) **is maintained** for reasons of record.

Applicants' arguments have been fully considered but fail to persuade. Applicant has amended claims 1, 17, 18 and 26 to include the transitional phrase "consisting essentially of " and "consists essentially of ". The amendment of claims to recite the transitional phrase "consisting essentially of " and "consists essentially of " does not overcome the instant rejection because the step of "passing a protein-contaning solution trough a filter" does not distinguish the claimed invention over the prior art. Applicant did not indicate in the specification or the claims how the steps "consisting essentially of passing a protein-contaning solution trough a filter" materially change the characteristics of Applicant's invention. Therefore, the rejection is maintained.

Nebe (WO 96/05846, IDS Paper No. 1) disclsoe the removal of prion form solution utilizing a series of membrane or ultramembrane filters. The method teaches using a prefilter of nylon gauze and nylon membrane filers ranging in size from 2 microns to 0.2 microns (see page 10). The filters can be arranged in a series. The reference indicated that prion particles can be

removed from the liquid and as an additional benefit at the same time other infectious martial can be removed such as bacteria, viruses and endotoxins (page 6). The reference also teaches that the prefilter alone removed half of the infectious agent (see page 13), indicating that the prion agent has a high binding affinity for the prefilter material. The reference also teaches that after the first ultra filtration alone the reduction in the prion protein was by a factor of $10^{4.67}$. The reference discloses that through the use a ultrafiltration the prion titer can be reduced even further, the process can be set up as series of filtration steps with each step further removing more of the infections prion protein. Nebe anticipates the instant invention.

New rejections

Claim Rejections - 35 USC § 112

Claims 1, 17, 18, 26, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to describe the mixtures of kieselguhr and perlite particles. The person of the ordinary skill in the art would unable to practice the instantly claimed invention without further guidance as to what are the proportions of kieselguhr and perlite particles in the mixtures as claimed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or

chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is the components of the mixture. There is no identification of any particular amounts or proportions of the of kiselguhr and perlite particles in the mixtures. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision any particular amounts or proportions of the of kiselguhr and perlite particles in the mixtures, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claims 1, 17, 18, 26, and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a matrix comprising kieselguhr or perlite particles, does not reasonably provide enablement for any mixtures of kieselguhr and perlite particles. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

One of skill in the art would not know how to make appropriate mixtures/proportions of kieselguhr and perlite without further guidance as to what are the exact proportions of kieselguhr and perlite in the mixture. The efficacy of the removal of the abnormal prion proteins using the mixtures of kieselguhr and perlite can vary depending on the proportions of the components of the matrix. Thus, the infective prion protein may not be successfully removed when any mixture of the kieselguhr and perlite is used. Foster (Transfusion Mediciene, 1999) discusses that abnormal prion protein binds a range of adsorbents resulting in partial or complete removal from the biopharmaceutical product. The abnormal prion protein reduction factor is determined by relative binding characteristics of the macromolecules to the prion particles and by the unit capacity of the absorbent as well as media used. Thus, the proportion of the kieselguhr and perlite in the matrix of the filter used for removal infective prion protein will affect the successful removal of the abnormal prion proteins from the sample. The instant specification does not provide guidance for how to use any mixtures of kieselguhr and perlite for successful removal of the abnormal prion proteins as claimed.

Conclusion

Applicant's amendment necessitated the new ground of rejections presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

June 28, 2006

Stacy B. Chen 6/28/06

Stacy B. Chen
Primary Examiner